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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,589	06/12/2007	Kazuhiro Kondo	64995(70904)	5282

21874 7590 01/09/2012
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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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01/09/2012

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/570,589	Applicant(s) KONDO, KAZUHIRO
	Examiner MARIA MARVICH	Art Unit 1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,8,11-13 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,8,11-13 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to an amendment filed 11/15/11. Claims 1, 7, 8, 11-13 and 17 are pending.

Response to Translation

The instant disclosure does not teach the limitations that the insert in a region corresponding to U2 through U8 and nucleotides 9041-17446 and in a region between U24 and U25 or nucleotides 36250-37775. The translation teaches on page 16 that the nucleotides are 10216-16457 of HHV-6. Further on pages 23-24, the nucleotides are listed as 9467-18041. Thus there is no disclosure of the instant invention as provided above. Hence, the Translation filed 11/15/11 is insufficient to establish an earlier priority date for the instant application.

Claim Objections

Claims 1, 11, 13 and 17 are objected to because of the following informalities: **This objection is maintained for reasons of record in the office action mailed 8/15/11.**

Claim 17 recites that “the exogenous nucleotide sequence is inserted inside a normal cell or an umbilical cord blood cell”. It is not clear if this means the method of producing is in said cells or if in addition to the insertion into the viral vector the exogenous nucleotide sequence is also inserted into the cell. The claim requires clarification as to which. In the case of the later, it would be proper to recite --is additionally inserted into the cell--. However, it is not clear why

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one would do so. If it is the former, it would be proper to recite, --the step of inserting is performed inside--.

These are new objections necessitated by amendment.

In claim 1, reordering the language would lead to a clearer understanding of the invention --that comprises the full-length sequence of HHV-6 Variant B and includes an exogenous nucleotide sequence--.

To be consistent, the phrases related to “a region corresponding to the U2 through U8 region” should be consistently recited as --(a) the region corresponding to the U2 through U8 regions-- and similarly the amendment of the U24 and U25 language should be amended. (see claim 1, 13 and 17).

When referencing previous limitations, it is proper to use the article --the--. When referring to HHV-6 throughout the claims after the first occurrence, it would be clearer to recite --the HHV-6--.

In claim 11, “varian” is a misspelling of --Variant--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Claim 13 recites that the exogenous nucleotides is inserted by

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way of homologous recombination that occurs between HHV-6 and a DNA sequence that is amplified with a variety of primers. However, there is no indication as to the relationship with the exogenous nucleotides. In other words, this will result in insert into the DNA sequence amplified but it is not clear where the exogenous nucleotides are.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7, 8, 11-13 and 17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kondo et al (abstract, 28th International Herpesvirus Workshop, July 26-31, 2003, 8.31). **This rejection is maintained for reasons of record in the office action mailed 8/15/11 and restated below.**

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. A translation of PCT/JP03/04553 is also required to ascertain that the designation that this application is a continuation of JP 2002-108550

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Kondo et al teach a recombinant HHV-6 viral vector comprising an exogenous nucleic acid encoding an enzyme as well as marker that is situated in the region between nucleotides 9041-17446 of SEQ ID NO:1.

Claims 1, 7, 8, 11-13 and 17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al (US 20080226677; see entire document). **This rejection is maintained for reasons of record in the office action mailed 8/15/11 and restated below.**

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. A translation of PCT/JP03/04553 is also required to ascertain that the designation that this application is a continuation of JP 2002-108550

Mori et al teach a recombinant HHV-6 viral vector comprising an exogenous nucleic acid encoding BAC and marker that is situated in the region between nucleotides 9041-17446 of SEQ ID NO:1 (see e.g. para 0018-0030).

Claims 1, 7, 11-13 and 17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hippenmeyer et al (US 5,972,666; see entire document). **This rejection is maintained for reasons of record in the office action mailed 8/15/11 and restated below.**

Hippenmeyer et al teach a recombinant HHV-6 vector comprising a deleted U25-U27 region which encompasses regions between 36250-37775 and U25 wherein sequences are inserted into the deleted region such as vaccine sequences (see figure 1).

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Response to Amendments

Applicants' arguments have been considered but are not persuasive. Regarding, Kondo et al, the recitation of "located in a region" corresponding to U2-U8 does not indicate the entirety of U2-U8. By inserting into the U3-U7 this is a region within U2-U8. The same is true of Mori et al. Mori et al teach that within HHV-6 U24, U25, U2, U3 etc. and by so arranging the insert place it within the U2-U8 region or the U24-U25 region.

Applicants argue that Hippenmeyer et al do not teach HV-6. However, as demonstrated below Hippenmeyer contemplates use of HHV-6 as well as other viruses. The model system is prepared according to figure 1 exemplified, however, applicants are not limited to examples but to what is disclosed as a whole. In this case, the invention is directed towards an assembly deficient virus, e.g. HSV/UL26/beta-gluc (see e.g. col 4, line 41-46). But is envisioned for other species such as HHV-6.

Most viruses encode proteinases that function in the processing of viral proteins during infection [W. G. Dougherty and B. L. Semler, Microbiological Reviews, 57:781-822 (1993)]. Biological and biochemical studies have shown that HSV-1 possesses a proteinase that can process another viral protein, the capsid assembly protein (also known as p40, ICP35 and VP22a). Similar proteinases are encoded in the genome of other members of the Herpesviridae. This family of DNA viruses includes HSV-1, HSV-2, human and simian cytomegalovirus (HCMV, SCMV), varicella-zoster virus (VZV), Epstein-Barr virus (EBV), human herpesvirus types -6, -7, and -8 (HHV-6, HHV-7, and HHV-8), pseudorabies virus (PRV), bovine herpesvirus (BHV), equine herpesvirus (EHV), and rhinotracheitis virus, among others.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

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Primary Examiner, Art Unit 1633